REMARKS

The Office Action mailed 23 December 2010 has been received and considered. Applicants have amended the claims of the application in an effort to overcome the rejections as set forth in the Office Action. Reconsideration of this application is therefore respectfully requested.

Rejection under 35 U.S.C. § 112:

Claim 34 stands rejected in view of its dependency from a cancelled claim, namely Claim 33. Responsive to the instant rejection, applicants have amended Claim 34 to depend from Claim 1. In view of this amendment, Claim 34 presently obviates the basis of the instant rejection. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103:

Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32 and 35 stand rejected under 35 U.S.C. §103(a) over McWha in view of Smith et al. (hereinafter "Smith"). Applicants respectfully traverse the rejection.

The independent claims of this application, namely claims 1, 16, 25 and 27, are individually directed to a flexible needle assembly which includes a flexible needle and a support needle. The flexible needle and the support needle are removably associated with one another. See paragraph [0021] line 9; and paragraph [0057] lines 1-3. The support needle defines a hollow lumen therein. The distal end of the support needle defines a pencil point tip and an opening which communicates with the hollow lumen.

Each of the independent claims provides that the flexible needle and the support needle are configured to be positioned in two conditions. In a first condition, the distal end of the support needle is positioned to extend beyond the leading edge of the flexible needle. The distal end of the support needle thereby provides a means whereby the flexible needle assembly may penetrate the skin of the patient. In a second condition, the support needle is removed from its

physical association with the flexible needle. This removal of the support needle from its association with the flexible needle may take several forms. In those embodiments wherein the support needle is positioned within a bore, defined in the flexible needle, the support needle is withdrawn from that bore. In those embodiments wherein the flexible needle is mounted on the exterior of the support needle, the support needle is detached from its association with the flexible needle.

Applicants respectfully submit that the combination of the McWha reference with the Smith reference, neither teaches nor suggests these particular limitations in applicants' claims.

McWha provides for a spinal needle 22 which is slidably positioned within the bore 14 of an epidural needle 12. McWha does not teach nor suggest that the spinal needle can be removed from its association with the epidural needle 12. Instead, McWha specifies that the spinal needle 22 is displaceable between a first position wherein the distal point 26 of the spinal needle 22 is substantially coincident with the open distal end 16 of the epidural needle 12 and a second position wherein the distal point 26 of the spinal needle projects a distance "x" beyond the open distal end 16 of the epidural needle 12. See Col. 4, lines 25-32; Col. 4, lines 43-50; Col. 6, lines 22-29.

The McWha device provides a threaded union of the spinal needle 22 and the epidural needle. By rotating the spinal needle, this threaded union is adapted to displace the spinal needle through the bore 14 and outwardly from the epidural needle thereby inserting the tip of the spinal needle into the subarachnoid space. A medicating agent is then passed through the interior lumen of the spinal needle and into the subarachnoid space. During the use of the McWha device, the spinal needle 22 is in constant physical association and contact with the epidural needle 12. McWha provides no teaching or suggestion that the spinal needle 22 is removable from its bore within the epidural needle 12. Furthermore, McWha provides no teaching or suggestion that the spinal needle 22 can be removed from its association or physical contact with the epidural needle. This is understandable in that the leading edge of the epidural needle is positioned within the patient's skin on one end and the retaining hub 30 of the spinal needle on the other end. It follows that the epidural needle is locked in place once the needle assembly is inserted into the patient.

Applicants respectfully submit that their claimed structure distinguishes over that of McWha. Applicants' structure requires that a support needle is removably associated with a flexible needle. This removability permits the support needle to be removed from the assembly once the needle assembly is inserted into the patient. After the support needle is removed, the bore previously occupied by the support needle is now free to receive a flow of medicating agent which passes through the bore and through the open end of the flexible needle into the patient.

Applicants' support needle is positionable in two conditions. In a first condition, the support needle is associated with the flexible needle such that the distal end of the support needle extends beyond the leading edge of the flexible needle. See FIG. 5. This first condition constitutes an insertion condition whereby the needle assembly may be inserted into the patient. Once the insertion has been accomplished, the support needle is then positioned in a second condition wherein the support needle is physically withdrawn from its association with the flexible needle. Once the support needle is withdrawn, this withdrawal opens up the internal bore within the flexible needle thereby permitting the clinician to direct a flow of medicating agent through the passageway of that bore.

The approach of McWha is quite different. In McWha, the combination of the spinal needle with the epidural needle, with the tip of the spinal needle being positioned coincident with the leading edge of the epidural needle, forms the insertion mode. Once the combination of the two needles is partially inserted within the patient, the clinician then rotates the spinal needle to extend the tip of the spinal needle outward from the epidural needle whereby that tip enters the subarachnoid space. Once the tip of the spinal needle has entered that space, the medicating agent is introduced through the interior of the spinal needle and thereafter outward through the opening in the spinal needle into the subarachnoid space. It should be noted that both the spinal needle and the epidural needle remain in place during all of this process.

In the McWha construction the internal needle of the two needle assembly, namely the spinal needle, is the needle through which the medicating agent flows. In applicants' needle assembly the medicating agent flows through the exterior needle (i.e. the flexible needle) after the internal needle, namely the support needle, has been removed. It follows that McWha provides a needle assembly in which both needles remain physically associated throughout, while

the applicants provide a needle assembly wherein the two needles are separated from one another after the initial insertion of the assembly and only the exterior needle remains in place while the medicating agent is administered to the patient.

Applicants respectfully submit that the claimed assembly is directed for use in a procedure which requires that the two needles be physically separated from one another during use to facilitate the operation of the assembly. McWha neither anticipates nor suggests the structure of applicants' claimed assembly as regards this separability aspect. Instead, McWha provides a two needle assembly wherein the two needles must remain physically associated with one another notwithstanding that the two needles may be displaced one relative to another. Furthermore, in McWha this displacement is limited to a displacement between two defined endpoints and not to a circumstance wherein the two needles are physically separated from one another.

Smith neither teaches nor suggests this particularly separability of the two needle elements. It follows that any combination of McWha with Smith would likewise neither teach nor suggest the claimed construction. In view of these considerations, applicants respectfully submit that Claims 1, 16, 25 and 27 distinguish over the combination of the McWha and Smith reference under the provisions of 35 U.S.C. §103(a). Similarly, all of the claims which depend either directly or indirectly from the independent claims likewise distinguish over the combination of McWha and Smith. Accordingly, applicants request the withdrawal of the rejection of these claims, and the claims which depend either directly or indirectly from these claims.

Claims 34, 36, 37 and 38 each requires that a plane containing the leading edge of the flexible needle is oriented perpendicularly to the longitudinal axis of the needle assembly. This particular feature is shown in FIG. 5 of applicants' drawings and is further referenced in paragraph [0037]. Applicants respectfully submit that this particular limitation is neither taught nor suggested in the combination of the McWha and Smith references. McWha teaches the configuration of a leading edge 34 which defines a bevel of 45 degrees across the axis A of the needle assembly. See FIG. 4 and discussion at Col. 4, lines 57-61. Alternatively, McWha defines a leading edge which is oriented at a smaller angle as shown in FIG. 4a and discussed at

Col. 4, lines 61-65. In either instance, McWha neither teaches nor suggests a leading edge in which a plane containing that leading edge is oriented perpendicularly to the axis of the needle assembly.

As described at paragraph [0037] the claimed leading edge orientation is important in that in applicants' needle assembly the tip of the support needle extends beyond the leading edge of the flexible needle and therefore that tip penetrates the patient's skin first and is then followed by the leading edge of the flexible needle. Since the flexible needle is disposed on the exterior of the support needle, it is important that the assembly of the flexible needle and the support needle provide a smooth transition at the location where the exterior surfaces of the two needles intersect. This transition assists in easing the penetration of the needle assembly into the patient. For this reason, the applicants have specified the provision of a leading edge which is oriented perpendicular to the axis of the needle assembly, i.e. the leading edge is contained within a plane which is disposed in a plane which is oriented perpendicularly to the axis of the needle assembly.

In contrast, McWha provides a structure wherein the leading edge of the epidural needle performs the initial penetration function while the tip of the interior spinal needle is positioned coincident with the leading edge. The McWha structure, in adopting a different approach to the penetration of the patient's skin, does not encounter the same concerns as the applicants' needle assembly. It follows that McWha does not provide a leading edge which is oriented perpendicular to the axis of the needle assembly. Similarly, Smith does not appear to provide any teaching of a perpendicularly oriented leading edge.

In view of these considerations, applicants respectfully submit that the instant claims distinguish over the combination of the McWha and Smith references. Accordingly, withdrawal of the instant rejections is respectfully requested.

Conclusion:

In view of the above considerations, applicants respectfully submit that the amended claims distinguish over the McWha and Smith references. Reconsideration and withdrawal of the rejections of applicants' claims is therefore respectfully requested.

Respectfully submitted,

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